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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/599,274	06/22/2000	Karl Andrew Garrill	PG4114	7879

23347 7590 01/25/2006

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EXAMINER

JOHNSON, JERROLD D

ART UNIT PAPER NUMBER

3728

DATE MAILED: 01/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/599,274	Applicant(s) <i>Gr</i> GARRILL ET AL.	
	Examiner Jerrold Johnson	Art Unit 3728	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply.

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>22 November 2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Double Patenting

Receipt of Terminal Disclaimers for 6,179,118 and 6,119,853 sent via facsimile on 12 January 2006 is acknowledged. Accordingly, this application now includes Terminal Disclaimers for these two patents as well as for 6,315,112; 6,390,291; 6,679,374 (10/071,674); 10/311,819; 10/312,073; and 09/971,799. There are no remaining Double Patenting rejections with respect to this Application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8 and 10-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Applicant's Admitted Prior Art (AAPA) in view of G. Williams and A. Tcherevatchenkoff "Moisture Transport into CFC-Free MDIS (1998) and Shichman et al. US 5,322,161.

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Drug products of the types claimed disposed in MDI pressurized containers having an HFA-134a propellant are set forth as Applicant Admitted Prior Art (AAPA) in this and commonly owned patents/applications (6,315,112; 6,390,291; 6,679,374 (10/071,674); 10/311,819; 10/312,073; and 09/971,799).

G. Williams and A Tcherevatchenkoff "Moisture Transport into CFC-Free MDIS (1998) discloses the vulnerability of such MDI pressurized containers having an HFA-134a propellant to moisture intrusion.

Shichman discloses the use of flexible packages within which medical products vulnerable to moisture are packaged along with desiccant packages appearing to be loosely held in the package so as to prohibit moisture damage to those products.

And, the specific nylon mesh desiccant package is set forth in page 5 of commonly owned co-pending application 10/311,819 as being commercially available prior art.

Accordingly, It would have been obvious to one of ordinary skill in the art to provide a flexible package and desiccant of the type claimed for the known prior art drug and HFA-134a propellant containing MDI so as prohibit moisture intrusion into the MDI.

Re claim 10, as AAPA discloses the nylon mesh sachet, and such sachets are well known to have a mesh size so as to not allow the loss of desiccant particles. And, as it is also known that the typical mesh size is smaller than the valve size in a typical MDI, it can be said that the AAPA desiccant filled nylon mesh sachet has desiccant particles that are larger than the valve size in the MDI.

Additionally, it is well known that desiccant particles are not for human consumption, and desiccant pouches typically include indicia to this effect. Accordingly, it would be obvious to one of ordinary skill in the art to prevent the likelihood of human consumption of the desiccant particles by making them too large to fit within the valve opening.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Applicant's Admitted Prior Art (AAPA) in view of G. Williams and A Tcherevatchenkoff "Moisture Transport into CFC-Free MDIS (1998) and Shichman et al. US 5,322,161, and further in view of Wilski et al. US 4,852,732.

Applicant's Admitted Prior Art (AAPA) in view of G. Williams and A Tcherevatchenkoff "Moisture Transport into CFC-Free MDIS (1998) and Shichman et al. US 5,322,161, as noted above, sets forth the claimed subject matter but does not disclosed a fixed desiccant sachet.

Wilski et al. US 4,852,732 discloses fixing a desiccant within a package.

Accordingly, it would have been obvious to one of ordinary skill in the art to fix a desiccant within a package so as to protect the desiccant and the product from excessive contact with each other.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerrold Johnson whose telephone number is 571-272-7141. The examiner can normally be reached on 9:30 to 6:00 M-F.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on 571-272-4562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JDJ

A handwritten signature, likely of the examiner, consisting of stylized initials.